

Serial No.: 09/746,880

Remarks

In the Office Action mailed March 27, 2002, claims 1-56 are pending in the application. Claims 6, 7, 16-19, 30, 31, 36-39, 42, 44 and 48 are withdrawn from consideration. Claims 1-5, 8-15, 20-29, 32-35, 40-42, 45-47 and 49-56 are rejected.

1. Election of Species

In the Office Action mailed March 27, 2002, the Examiner states that the Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner believes that, as currently presented, claims 1-15, 20-35 and 40-56 are generic. Applicants affirm their previous election of claims 12, 32, 51 and 43.

2. Rejection of Claims as Obvious Over Krzysik in View of Beerse

In the Office Action mailed March 27, 2002, the Examiner rejects claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,294,186 to Beerse et al. (hereinafter "the Beerse patent"). A *prima facie* case of obviousness has not been established and therefore, Applicants respectfully traverse the rejection.

With respect to claims 1, 5, 8, 10, 11, 14, 15, 20, 25, 26, 29, 34, 35, 40, 47, 50, 52 and 53, the Examiner believes the Krzysik patent discloses an absorbent article including a topsheet, a backsheet and an absorbent core located in between the topsheet and the backsheet. The Examiner believes the Krzysik patent discloses a lotion composition on the topsheet where the lotion composition is melted, applied to the topsheet and then cooled. The Examiner also believes the Krzysik patent discloses the lotion composition including 5-95% emollient, 0.1-25% of a viscosity enhancer and 5-95% of a wax, which can be a natural oil such as hydrogenated cottonseed oil. The Examiner acknowledges that the Krzysik patent does not disclose a lotion composition including a sterol and a decoupling polymer.

The Examiner believes the Beerse patent discloses a lotion composition that can be used on diapers and is based on an emollient containing 0.1-10% of a decoupling polymer such as polysaccharides or polyacrylamides, a clay and 0.1-20% of a skin moisturizer such as sterol cholesterol. The Examiner believes it would have been obvious to one having

Serial No.: 09/746,880

ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to include the decoupling agent, clay and the sterol of the Beerse patent in order to thicken the skin care composition to improve the moisturizing effect of the composition.

With respect to dependent claims 2, 22, 41 and 55 (viscosity of compositions), the Examiner refers the Applicants to col. 12, lines 42-58 of the Krzysik patent. With respect to dependent claims 3, 27 and 45 (selection of emollient), the Examiner refers the Applicants to col. 9, lines 45-50 of the Krzysik patent. With respect to claims 4, 28 and 46 (selection of viscosity enhancer), the Examiner refers the Applicants to col. 10, lines 48-67 of the Krzysik patent. With respect to claim 9 (selection of natural fat or oil), the Examiner refers the Applicants to col. 10, lines 19-33 of the Krzysik patent. With respect to claims 12, 13, 32, 33 and 51 (inclusion of a rheology modifier and its selection), the Examiner believes the Krzysik patent discloses the use of a rheology modifier such as silica. With respect to claims 21 and 54 (melting point of compositions), the Examiner refers the Applicants to col. 12, lines 29-34 of the Krzysik patent. With respect to claims 23 and 56 (penetration hardness of compositions), the Examiner refers the Applicants to col. 12, line 66 to col. 13, line 2 of the Krzysik patent. With respect to claim 24 (amount of composition), the Examiner refers the Applicants to col. 13, lines 42-55 of the Krzysik patent. With respect to claim 43 (application by slot coating), the Examiner refers the Applicants to col. 13, line 59 of the Krzysik patent.

Claim 1 of the present invention is directed to an absorbent article including an outer cover, a liquid permeable bodyside liner and an absorbent body that is located between the bodyside liner and the outer cover. The bodyside liner defines a bodyfacing surface and is connected in superposed relation to the outer cover. The article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner. The composition includes from about 40 to about 95 weight percent of emollient; from about 0.1 to about 40 percent by weight of viscosity enhancer; and from about 0.1 to about 20 percent by weight of decoupling polymer. Claim 15 of the present invention is similar to claim 1 and further includes that the decoupling polymer may be selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphatoethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such

Serial No.: 09/746,880

compounds.

Claim 20 of the present invention is also similar to claim 1 except the composition includes from about 0.1 to about 95 percent by weight of natural fats or oils; from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; and from about 1 to about 95 percent by weight of emollient; from about 0.1 to about 40 percent by weight of viscosity enhancer; and from about 0.1 to about 20 percent by weight of decoupling polymer. Claim 35 of the present invention is similar to claim 20 except the decoupling polymer may be selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds.

Claim 40 of the present invention is directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method includes a step of heating a composition including an emollient, a viscosity enhancer and a decoupling polymer. The composition is heated to a temperature above the melting point of the composition where the composition has a melting point of from about 32°C to about 100°C. The method includes a step of applying the composition to a bodyfacing surface of a bodyside liner of an absorbent article and a step of resolidifying the composition. Claim 53 of the present invention is directed to a method for protecting the skin barrier on a skin surface of a user. The method includes a step of contacting the skin surface of the user with a bodyfacing surface of a liner material where the bodyfacing surface has a composition including an emollient, a viscosity enhancer and a decoupling polymer. The method also includes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface and a step of repeating the contact for a sufficient period of time to protect the skin barrier. The composition includes from about 1 to about 95 weight percent of an emollient; from about 1 to about 40 percent by weight of a viscosity enhancer; and from about 0.1 to about 20 percent by weight of decoupling polymer selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate),

Serial No.: 09/746,880

poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner has not identified why one of ordinary skill in the art would have been motivated to combine the disclosures of the Krzysik and Beerse patents. The Examiner states she believes it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to include the decoupling agent, clay and the sterol of the Beerse patent, but she does not identify any specific disclosure of the references that would lead to such a combination. The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention.

The Krzysik patent relates to absorbent articles that include a lotionized bodyside liner for improved skin health benefits. (See Col. 1, lines 7-12). Conversely, the Beerse patent relates to antimicrobial compositions that provide immediate and residual anti-viral and antibacterial efficacy. (See Col. 1, lines 44-46). The Examiner does not explain why one of skill in the art would have been motivated to include the "thickening agents" and "skin moisturizing agents" of the Beerse patent in the lotion compositions of the Krzysik patent- particularly in view of the large number of groups of compounds disclosed in the Beerse patent. Additionally, no suggestion or motivation is identified for picking elements from the Beerse patent to arrive at a composition that reduces the irritation response of skin to the enzymes in biological fluids as occurs with the compositions claimed by the present invention. The requisite motivation cannot be derived from the Applicants' specification.

Further, it may be undesirable to modify the Krzysik compositions according to the disclosure of the Beerse patent. This is because it may be highly undesirable to use components of an antiviral/antibacterial composition to improve the skin health of wearers of absorbent articles because such compositions could kill naturally-occurring beneficial flora that protect the skin. If a proposal for modifying the prior art in an effort to attain the

Serial No.: 09/746,880

claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed.

With respect to the second element of a *prima facie* case of obviousness, the combination of the Krzysik and Beerse patents does not provide the required expectation of succeeding at the endeavor of the present invention to improve the barrier function of the skin, particularly in view of the potentially deleterious effect of antimicrobial compositions on the skin. Additionally, neither of the cited references recognize the "result-effective" capability of the decoupling polymers of the present invention.

With respect to the third element of a *prima facie* case of obviousness, the combination of the Krzysik and Beerse patents does not disclose or suggest each element of the presently claimed invention. With respect to claims 2 and 22, the Examiner believes the Krzysik patent discloses a lotion formulation having a low shear viscosity between 50,000 and 80,000 centipoise and a high shear viscosity between 150 and 200 centipoise. While the Krzysik patent discloses lotion formulations having ranges of viscosities (see Col. 12, lines 41-59), the Krzysik patent does not teach or suggest the claimed viscosity ranges under low shear or high shear conditions. Second, with respect to claim 53, the combination of the Krzysik and Beerse patents does not disclose a method for protecting the skin barrier on a skin surface of a user (using the claimed composition) that includes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface and a step of repeating the contact for a sufficient period of time to protect the skin barrier. For at least these reasons, the Applicants submit that claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56 are patentable over the Krzysik patent in view of the Beerse patent.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of pending claims 1-5, 8-15, 20-29, 32-35, 40, 41, 43, 45-47 and 49-56. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-2433.

The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be

Serial No.: 09/746,880

Marked-up version showing changes

The insult solution is prepared by diluting a 10 mg/ml stock solution in phosphate-buffered saline to a working concentration of 250 μ g/ml. The base of the stock solution is 50 mM NaOAcetate, pH 5.5 and 0.15 M NaCl stored at -80°C. One ~~milliliter~~ milligram of the stock protease insult ~~solution~~ contains 2558 USP units of trypsin and 298 USP units of chymotrypsin and is available from Specialty Enzymes, Inc. of Chino, CA. The bile acid insult solution can be prepared by dissolving 65 mg of cholic acid, 62 mg of deoxycholic acid and 31 mg of chenodeoxycholic acid in 10 ml of phosphate-buffered saline. The bile acid insult components can be purchased from Sigma Chemical Co. of St. Louis, MO. Phosphate-buffered saline, pH 7.4 (hereinafter "PBS") can be purchased from Life Technologies of Rockville, Maryland.